Perspectives on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy

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WTO rules on non-discrimination by field of technology create problems for patent policy.

Article 27: *Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, **in all fields of technology**, provided that they are new, involve an inventive step and are capable of industrial application.[1] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and **patent rights enjoyable without discrimination** as to the place of invention, **the field of technology** and whether products are imported or locally produced.

[1]For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Areas where patents are not needed

- Software
- Business methods
- Surgical procedures

Areas where Exclusive Rights models are not the best instrument for incentives

- Research tools
- Complex biotech inventions
- Rights in data

Some concerns about Public/Private cooperation

- Public Private Partnerships
  - "Big pharma" Pharmaceutical cartels on AIDS pricing, and control of public sector R&D
- ICANN
  - Management of Cartel or self regulation?

DOJ/FTC joint venture guidelines

- Do not reflect impact of joint ventures and collaborative ventures on competition
  - Need new metric to supplement HHI for industries with extensive licensing, joint venture and other collaborative ventures.
  - Music industry
  - Pharmaceutical companies
  - Software

We need lower hurdles for pro-competitive conduct remedies

- Abuse of market power tests should be lower
- Rules that have substantial probability of pro-competitive results should be easier to impose.
  - Microsoft
  - Compulsory licensing

The explosion of *sui generis* rights are important barriers to competition

- Article 39.3 of the TRIPS and Hatch/Waxman data exclusivity
- Orphan Drug marketing exclusivity
- Pediatric patent extensions
- Proposed US *sui generis* database

US Orphan Drug Act

- Initially designed to encourage marketing of existing medicines with small markets, with emphasis on moral suasion.
- Attention shifted to R&D, and public subsidies for research, subject to needs test.
- Companies eliminated needs test, and obtained very strong exclusive rights.

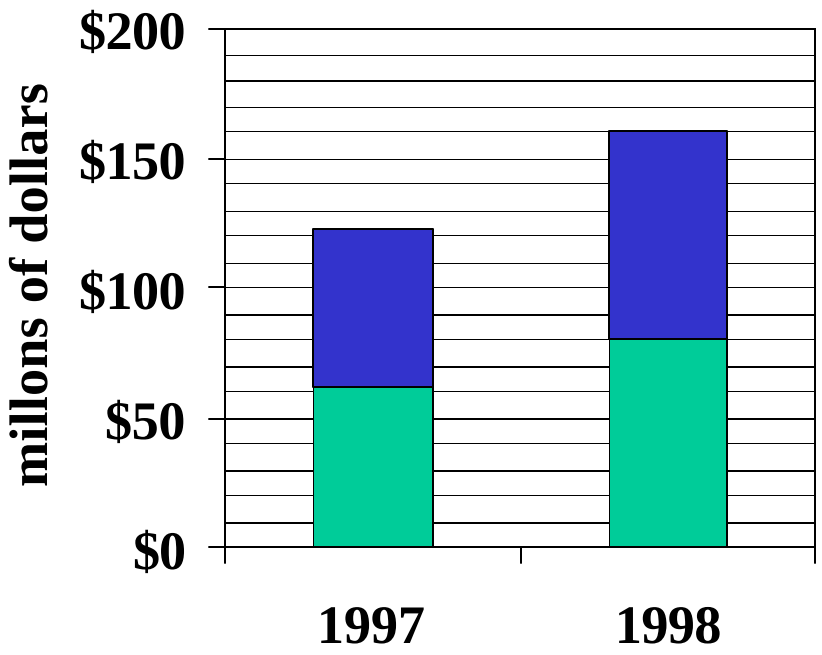
Orphan Drug Act Incentives

- Available by indication, for client population of 200,000 or less
- FDA managed grant program
- Tax credit for 50 percent of the cost of trials
  - (all US and some foreign trials).
- Seven years marketing exclusivity.

Orphan Drug Tax Credit

1998-1999

Expenditures on Clinical Trials for Orphan drugs



- Total expenditures
  - $283 million before taxes
  - 141 million after taxes
- 36 Orphan approvals (39 indications)
- Expenditures per approval
  - $7.9 million per before taxes
  - $3.9 million after taxes

Some drugs that have benefited from US Orphan Drug law

- Paclitaxel
- Oxandrolone
- Gleevec
- AZT
- Epogen and Neuogen
- Ceredase

How important are orphan drugs in the US?

- Varies from year to year.
- In 1998, of the 30 FDA approved new molecular entities, 7 were classified as orphans, or 23 percent of the total.

Pediatric Exclusivity

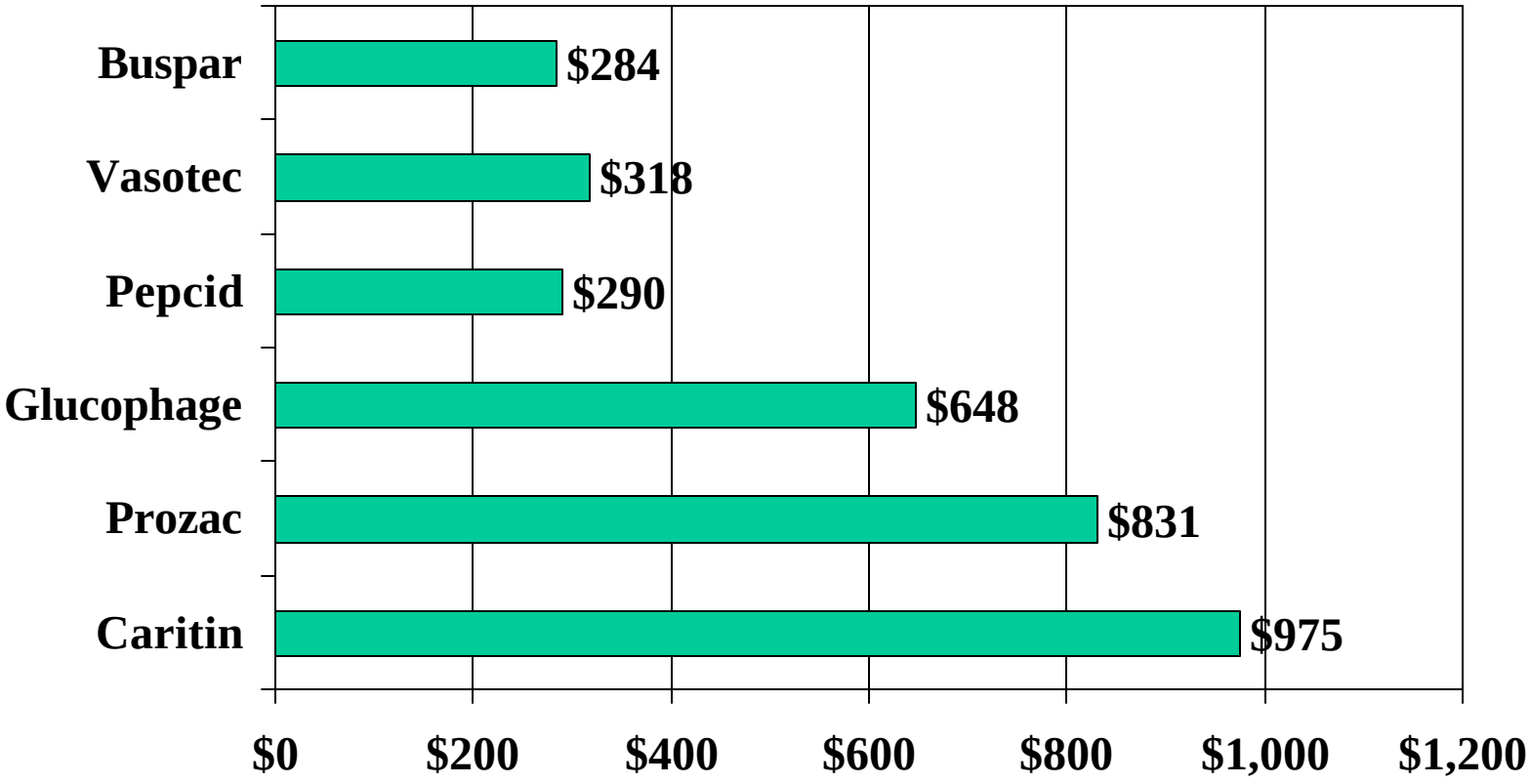
- In return for clinical trials on children, companies can obtain six months of marketing exclusivity.
- Required tests can involve small numbers of children.
- Very expensive in terms of cost to consumers, in return for very modest private sector costs.

What do we get from the companies for the 6 months Pediatric Exclusivity?

"The studies required to gain six more months of marketing exclusivity are relatively small and inexpensive, costing anywhere from $200,000 to $3 million. But the extended exclusivity that results can be very valuable. It will boost drug-company sales by more than $4 billion, by the Journal's calculations, which compare six months of sales while a drug has marketing exclusivity against typical six-month sales of the drug after generic competition hits."

Drug Makers Find a Windfall Testing Adult Drugs on Kids, Rachel Zimmerman, WSJ, Feb 2001

WSJ estimate of Company Benefits of Pediatric Exclusivity



R&D is important, and costs money

What do companies spend on R&D?

7.5 percent of sales

Pre-clinical research can be difficult, risky and costly

TB Alliance Report on economics of TB drug development

- Drug Development Costs:
  - The costs--including the costs of failure--to develop a new chemical entity (NCE) to treat TB are estimated to be approximately $76 million to $115 million, including preclinical development, pharmaceutical development, and clinical trials. Including rough estimates of discovery brings the estimated total to between $115 million and $240 million (including the costs of failure). (All values are in U.S. dollars.)

How to fund R&D?

Property rights in IP

- Advantages
  - Works without appropriations
  - Decentralized decision making
  - Encourages risk taking
- Disadvantages
  - Excessive secrecy
  - Ethical concerns over pricing
  - Bargaining failures can block product development
  - Under investment in public health priorities

Alternative funding models

- Public funding and subsdies
- Research mandates

Efforts to reexamine IPR system in high tech economy

- National Academy of Sciences
- FTC on IPR and antitrust
- EU debate over software patents
- Unrest among users
  - Research tools
  - Future of music
  - Free software movement
  - Challenge to US copyright extension
  - Access to public documents on the Internet
  - Access to scientific journals

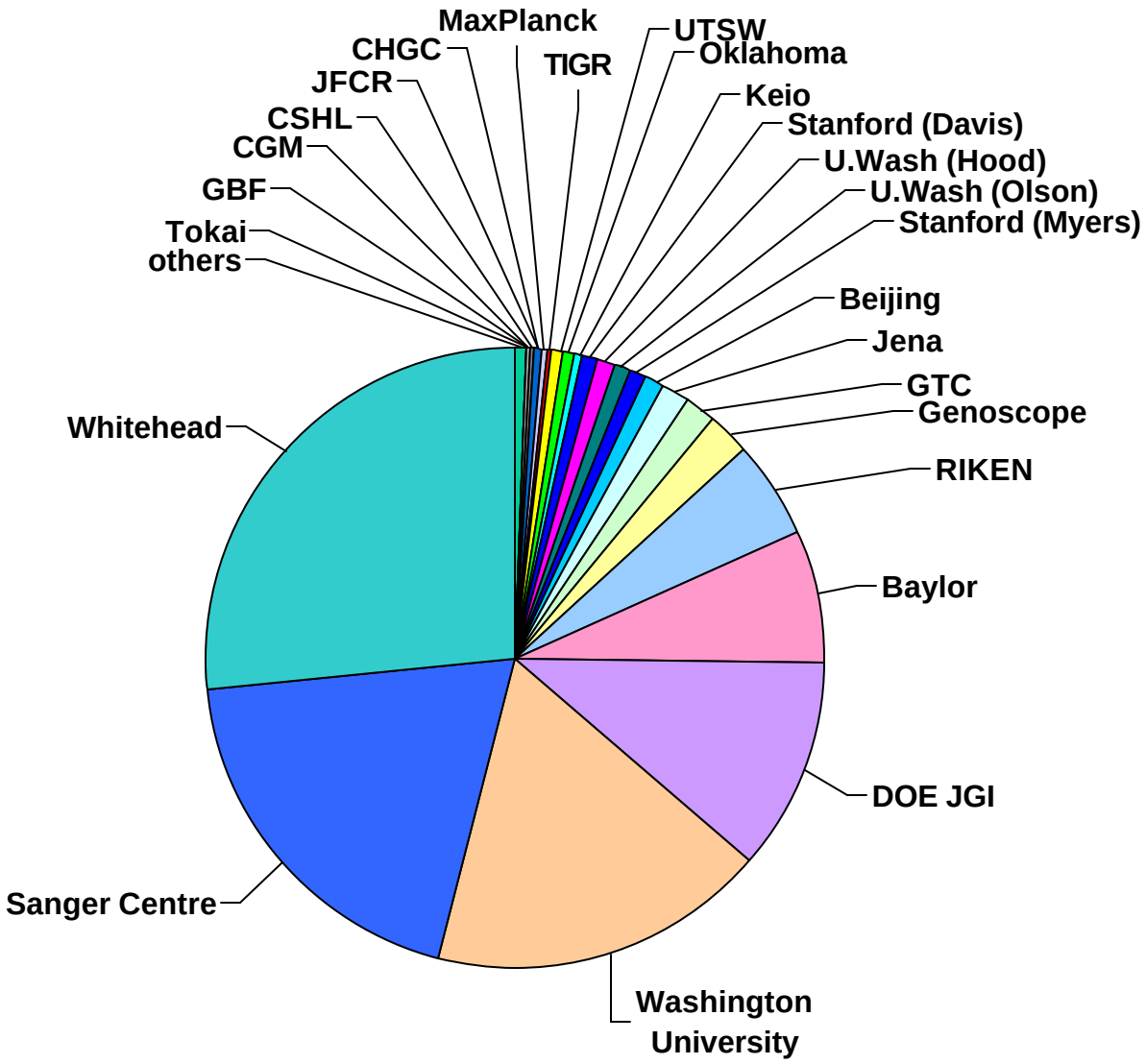
Collective intelligence

- Eric Raymond's the Cathedral and Bazaar broadened interest in the benefits of collaborative research models.
- Human Genome project

GNU General Public License (GPL)

- For copyrighted materials, you can use freely even for commercial purposes, but must share modified code.
- Efforts to extend to patent or data.

Human Genome Sequencing



Tim Hubbard on Effect of restrictions on access to biological data

- Biology is too complex for any organisation to have a monopoly of ideas or data
- When company starts a new project: "Most research is being done elsewhere"
- If blocks of biological data are held privately, even if they pay for access, companies miss out on the analysis that would be published by other scientists, if they too had access to this data.
- The fewer people analysing a block of data, the less valuable it is.

Tim Hubbard on Options to moderate monopoly effects of gene patents

- Do not allow gene based patents
  - Already much more difficult
  - Patent law currently being reviewed at WIPO, WTO
- Make compulsory licensing easier and less costly
  - A government or a judge issues a non-voluntary license to use a patent.
  - Compulsory licensing can introduce competition and lower prices.
  - Compulsory licensing can prevent a patent holder from blocking R&D and/or the development of new products.

Compulsory licenses and patent pools

“In 1917, as a result of recommendation of a committee formed by the Assistant Secretary of the Navy (The Honorable Franklin D. Roosevelt), an aircraft patent pool was privately formed encompassing almost all aircraft manufacturers in the United States.9 The creation of the Manufacturer's Aircraft Association was crucial to the U.S. government because the two major patent holders, the Wright Company and the Curtiss Company, had effectively blocked the building of any new airplanes, which were desperately needed as the United States was entering World War I.10”

GPL type approach to Public Funded Patents?

- Should US agencies preserve researcher access as condition of public funding of inventions?

Doha Declaration

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

   In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The US approach to Paragraph 6 of the Doha Declaration on TRIPS is anti-consumer

- US seeks to limit exports of medicines to limited cases.
- Often economies of scale and scarce technology make it impractical to have large numbers of suppliers of goods
- Article 31.f of TRIPS is limitation of exports without consent of right owner.
- Exceptions to 31.k for anticompetitive practices still present problems
- Some inventions should be distinguished and exports permitted, where rights of patent owner are protected in country of consumption.
- US Trade policy shaped too much by export industries.

What would a trade agreement look like if designed by public health officials?

It would be different than the TRIPS

- Focus on innovation
  - Greater attention to outcomes and health care priorities
  - More transparency of investment flows
- Consider a wider range of instruments
    - Property rights would be a means, not an end
    - Public sector research would be addressed
    - Other tools to promote R&D would be considered
- Promote access to medicines, technology transfer and capacity building for R&D
- Greater attention to efficiency

Trade Discussions involving R&D

- Regional and bilateral
  - Treaty establishing the European Community.
  - EU/Israel Scientific and Technological Cooperation Agreement
- Weapons
  - Convention on the Prohibition of the use, Stockpiling, Production and Transfer or Anti-Personnel mines and on their destruction. Also, Comprehensive Test Ban Treaty, 1972 treaty on Biological weapons.
- Kyoto Protocol to the UN Framework convention on climate change.
- Health
  - G8 discussions of R&D on neglected diseases

Models for R&D trade frameworks on health care

- Clinton/Blair agreement on funding sequencing of the human genome.
- G8 discussions on research for neglected diseases
- Several proposals for treaty on R&D on vaccines.
- Possible agreements on public access to journals
- Proposals to let WHO use government funded patents
- Discussions on benefit sharing when R&D takes place in developing countries